

Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
*Joint Cardiovascular and Renal Drugs and
Drug Safety and Risk Management Advisory Committees*
December 8, 2009
Hilton Washington DC North/Gaithersburg,
620 Perry Parkway, Gaithersburg, MD.

draft Agenda

8:00 a.m.	Call to Order Introduction of Committee	Robert Harrington, M.D. Chair, CRDAC
	Conflict of Interest Statement	Elaine Ferguson, M.S.,R.Ph. Designated Federal Official, CRDAC

The committees will discuss safety considerations related to FDA approved gadolinium-based contrast agents used with magnetic resonance imaging (MRI) scans. An MRI is a medical imaging technique that does not require x-rays. These scans outline the internal body structures such as organs and other soft tissues. Contrast agents are substances injected into the body before MRI scans, helping doctors to better see and interpret MRI findings. FDA approved gadolinium-based contrast agents include: gadobenate dimeglumine (MULTIHANCE), gadodiamide (OMNISCAN), gadopentetate dimeglumine (MAGNEVIST), gadoteridol (PROHANCE), gadoversetamide (OPTIMARK), gadoxetate disodium (EOVIST), and gadofosveset (ABLAVAR, previously known as VASOVIST).

8:05 a.m.	FDA Opening Remarks	Ira Krefting, M.D. Medical Officer, Division of Medical Imaging and Hematology Products, CDER, OND, OODP
8:15 a.m.	Guest Speaker Histology, Pathology, NSF Registry	
8:45 a.m.	Guest Speaker Clinical Imaging	
	<u>Sponsor Presentations:</u>	
9:15 a.m.	Bayer Magnevist (Gadopentetate Dimeglumine)	Christiane Pering, MD, PhD, Vice President, Head of Global Medical Affairs Diagnostic Imaging, Bayer
9:35 a.m.	Bracco Diagnostics Inc Prohance	Alberto Spinazzi, MD, Sr VP, Worldwide Medical and Regulatory Affairs, Bracco Diagnostics Inc.

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9:55 a.m.	GE Healthcare Joint Meeting of the Cardio-Renal and Drug Safety and Risk Management Advisory Committees Safety of Omniscan™ (gadodiamide) Injection for Intravenous Use "	Eric Cantor, MD Head, Medical Professional Services, GE Healthcare
10:15 a.m.	Covidien Pharmaceuticals Optimark – Presentation to the Joint Meeting of the Cardiovascular and Renal Drugs and Drug Safety and Risk Management Advisory Committee	Herbert Neuman, MD Chief Medical Officer Vice President Medical Affairs Covidien Pharmaceuticals
10:35 a.m.	Break	
10:50 a.m.	Bracco Diagnostics Inc Multihance	Alberto Spinazzi, MD, Sr VP, Worldwide Medical and Regulatory Affairs, Bracco Diagnostics Inc
11:10 a.m.	Bayer Eovist (Gadoxetic Acid, Disodium)	Christiane Pering, MD, PhD, Vice President, Head of Global Medical Affairs Diagnostic Imaging, Bayer
11:30 a.m.	Lantheus Medical Imaging, Inc. "Benefit-Risk Update: Ablavar."	E. Kent Yucel, M.D. Professor of Radiology Tufts University
11:50 a.m.	<u>FDA Presentations</u> Chemistry Considerations Gadolinium Based Contrast Agents	Eldon Leutzinger, PhD and David Place, PhD Office of New Drug Quality Assessment FDA
	Drug Utilization Analysis of Gadolinium-Based Contrast Agents	Grace Chai, PharmD Office of Surveillance and Epidemiology
	Epidemiology Literature Review on Review of Gadolinium-Based Contrast Agents	Julia Ju, PharmD, PhD Office of Surveillance and Epidemiology
	Title (to be determined)	Jim Kaiser, MD Office of Surveillance and Epidemiology

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- 1:00 p.m. Lunch
- 2:00 p.m. Open Public Hearing Session - will
 be moved to 1:00 p.m. if possible.
- 3:00 p.m. Committee Discussion and Answer
 Questions
- 4:00 p.m. Break
- 4:15 p.m. Committee Discussion and Answer
 Questions
- 5:00 p.m. Adjourn

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